

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FWK Holdings, L.L.C., on behalf of itself and all
others similarly situated,

Plaintiff,

v.

ACTAVIS ELIZABETH, LLC, TEVA
PHARMACEUTICALS USA, INC., PLIVA, INC.,
MYLAN INC., MYLAN PHARMACEUTICALS
INC., UDL LABORATORIES, INC.; PAR
PHARMACEUTICAL, INC., HERITAGE
PHARMACEUTICALS INC., BRECKENRIDGE
PHARMACEUTICAL, INC., and UPSHER-
SMITH LABORATORIES, INC.,

Defendants.

CÉSAR CASTILLO, INC., individually and on
behalf of all those similarly situated,

Plaintiff,

v.

ACTAVIS ELIZABETH, LLC,
BRECKENRIDGE PHARMACEUTICAL, INC.,
HERITAGE PHARMACEUTICALS INC.,
MYLAN INC., MYLAN
PHARMACEUTICALS INC., PAR
PHARMACEUTICAL, INC., PLIVA, INC.,
TEVA PHARMACEUTICALS USA, INC.,
UDL LABORATORIES, INC., and UPSHER-
SMITH LABORATORIES, INC.,

Defendants.

Civil Action No. 1:16-cv-09901-JSR

Hon. Jed. S. Rakoff

**CONSOLIDATED AMENDED DIRECT
PURCHASER CLASS ACTION
COMPLAINT**

JURY TRIAL DEMANDED

Civil Action No. 1:17-cv-00078-JSR

Hon. Jed. S. Rakoff

REDACTED PURSUANT TO FEBRUARY 6, 2017 PROTECTIVE ORDER

TABLE OF CONTENTS

	Page(s)
I. INTRODUCTION	1
A. Defendants Who Sold Propranolol Capsules Drastically Increased Their Prices...	2
B. Defendants Who Sold Propranolol Tablets Increased Their Prices by an Extraordinary Amount.	3
C. Defendants’ Generic Drug Prices Increases Are Being Investigated by the DOJ, the U.S. Congress, and 40 States’ Attorney General.	3
D. Receipt of Grand Jury Subpoenas and Other Information Requests from Government Entities.	10
II. PARTIES	11
A. Agents and Co-Conspirators	15
III. JURISDICTION AND VENUE	16
IV. INTERSTATE TRADE AND COMMERCE	17
V. FACTUAL ALLEGATIONS	18
A. Overview of the Generic Drug Market	18
1) Generic drugs should lead to lower prices	18
2) Pricing of Generic Pharmaceuticals	20
B. The DOJ and 40 States’ Attorneys General Are Investigating How Generic Drug Companies Utilized Trade Associations to Reach Illegal Agreements	22
1) Generic Pharmaceutical Association	22
2) Healthcare Distribution Management Association	24
3) Minnesota Multistate Contracting Alliance for Pharmacy	24
4) National Association of Chain Drug Stores	25
5) National Pharmacy Forum	25
6) Efficient Collaborative Retail Marketing	26

7)	Defendants Opportunities for Collusion	26
C.	Propranolol Prices Soar.....	42
1)	Defendants Who Sold Propranolol Capsules Drastically Increased Their Prices.....	42
i)	Breckenridge	48
ii)	Actavis	48
iii)	Upsher-Smith	49
2)	Defendants Who Sold Propranolol Tablets Increased Their Prices by an Extraordinary Amount.	50
i)	Heritage.....	54
ii)	Teva.....	55
iii)	Actavis	56
iv)	Mylan	57
v)	Par	57
3)	Medicaid Reimbursement Data Reflects Defendants’ Price Increases.....	59
4)	Defendants’ Price Increases Were Against Their Self-Interest	66
5)	There Were No Shortages Reported to the FDA	66
VI.	THE PROPRANOLOL MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION.....	68
VII.	ABSENCE OF WORLDWIDE COST INCREASES	75
VIII.	CLASS ACTION ALLEGATIONS	75
IX.	ANTITRUST INJURY	78
X.	VIOLATION OF THE SHERMAN ACT § 1	79

Plaintiffs FWK Holdings, L.L.C. (“FWK”) and César Castillo, Inc. (“CCI”) (together, “Plaintiffs”), on behalf of themselves and all others similarly situated, against: 1) Actavis Elizabeth, LLC; 2) Teva Pharmaceuticals USA, Inc., and Pliva, Inc. (together defined below as “Teva”); 3) Mylan Inc., Mylan Pharmaceuticals Inc., and UDL Laboratories, Inc. (together defined below as “Mylan”); 4) Par Pharmaceutical, Inc. (“Par”); 5) Heritage Pharmaceuticals Inc.; 6) Breckenridge Pharmaceutical, Inc.; and 7) Upsher-Smith Laboratories, Inc. (collectively, the “Defendants”) allege as follows based upon information and belief¹, except as to the allegations pertaining to Plaintiffs and the allegations based upon certain data obtained from non-parties, documents produced by non-parties in this Action, and certain publicly available information:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants’ unlawful scheme to fix, maintain, and stabilize the prices, rig bids and allocate customers for generic propranolol tablets and capsules (collectively, “Propranolol”).

2. Propranolol is the generic version of Inderal. The U.S. Food and Drug Administration approved Inderal, developed by Wyeth Pharmaceuticals, Inc., in 1967.

3. Propranolol is a beta-blocker. Beta-blockers affect the heart and circulation (blood flow through arteries and veins). Propranolol is used to treat tremors, angina (chest pain), hypertension (high blood pressure), heart rhythm disorders, and other heart or circulatory

¹ The Complaint pleads facts alleged upon information and belief where the facts are peculiarly within the possession and control of Defendants. *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (“The *Twombly* plausibility standard, which applies to all civil actions, *see Iqbal*, 129 S.Ct. at 1953, does not prevent a plaintiff from “pleading facts alleged ‘upon information and belief’” where the facts are peculiarly within the possession and control of the defendant . . .”).

conditions. It is also used to treat or prevent heart attack, and to reduce the severity and frequency of migraine headaches. Propranolol is reportedly the highest-selling beta-blocker as measured by prescriptions.

4. As alleged below, Defendants' scheme injured Plaintiffs and the Classes of direct purchasers they seek to represent (as defined below), causing them to pay overcharges. Plaintiffs seek to recover these overcharges and seek other relief arising out of Defendants' conspiracy to charge supra-competitive prices for: 1) propranolol capsules during the period from November 14, 2013 to the present ("Propranolol Capsules Class Period"), and 2) propranolol tablets during the period from January 2015 to the present ("Propranolol Tablets Class Period").

5. Based on the conduct alleged herein, Plaintiffs allege that during the Class Periods, Defendants combined, conspired and contracted to fix, raise, maintain and stabilize prices at which propranolol would be sold in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

6. In addition, as alleged herein Defendants agreed to allocate products and customers in violation of Section 1 of the Sherman Act.

7. As a result of Defendants' unlawful conduct, Plaintiffs and the other members of the Classes paid artificially inflated prices that exceeded the amount they would have paid if a competitive market had determined prices for propranolol.

A. Defendants Who Sold Propranolol Capsules Drastically Increased Their Prices.

8. Beginning in November 2013, contrary to a well-established past practice, Defendants Actavis, Breckenridge, and Upsher-Smith ("Capsule Defendants") increased the price of propranolol capsules dramatically, as alleged below in Paragraphs 146-73. The increases were the result of an agreement among the Capsule Defendants to increase pricing, restrain competition, and allocate customers for the sale of propranolol capsules in the United States. As alleged below,

the agreement was furthered by discussions held at various trade association meetings and events, including, but not limited to, meetings and events held by: 1) the National Association of Chain Drug Stores (“NACDS”); 2) the Generic Pharmaceutical Association (“GPhA”); 3) Efficient Collaborative Retail Marketing (“ECRM”); 4) the National Pharmacy Forum (“NPF”); 5) the Minnesota Multistate Contracting Alliance for Pharmacy (“MMCAP”); and 6) the Healthcare Distribution Management Association (“HDMA”).

B. Defendants Who Sold Propranolol Tablets Increased Their Prices by an Extraordinary Amount.

9. For years, Defendants Actavis, Heritage, Mylan, Par, and Teva (“Tablet Defendants”) charged pennies per tablet for propranolol tablets. By at least the beginning of the Propranolol Tablet Class Period, the Tablet Defendants caused the price of propranolol tablets to dramatically increase, as alleged in Paragraphs 174-212. The increases were the result of an agreement among the Tablet Defendants to increase pricing and restrain competition for the sale of propranolol tablets in the United States. As alleged below, the agreement was furthered by discussions held at trade association meetings and events, including NACDS, GPhA, ECRM, NPF, MMCAP and HDMA meetings and events.

C. Defendants’ Generic Drug Prices Increases Are Being Investigated by the DOJ, the U.S. Congress, and 40 States’ Attorney General.

10. Defendants’ dramatic and unexplained price increases have resulted in extensive scrutiny by federal and state regulators, including by the Antitrust Division of the United States Department of Justice (“DOJ”), the United States Senate, the United States House of Representatives, and 40 States’ Attorneys General.

11. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several generic drug manufacturers, including Defendants Actavis, Heritage, Mylan and Teva.

12. On November 20, 2014, Senator Sanders's committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?" Various witnesses discussed the price increases for generic drugs. No chief executive of a generic drug manufacturer testified.

13. The DOJ is currently conducting a wide-ranging criminal investigation into collusion among generic drug companies. According to *Bloomberg News*, the investigation reportedly covers more than 12 companies and at least 24 drugs.

14. According to a June 26, 2015 report by the service Policy and Regulatory Report ("PaRR Report") (available at <http://www.mergermarket.com/pdf/DoJCollusion-Generic-Drug-Prices-2015.pdf>):

A PaRR source says prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department's largest criminal antitrust probe ever. Like in that case, prosecutors expect "to move from one drug to another in a similar cascading fashion."

15. On December 14, 2016, the DOJ unsealed criminal Informations against Heritage's Jason T. Malek (former Senior Vice President, Commercial Operations, and subsequently President) and Jeffrey A. Glazer (former CEO and Chairman) for violations of Section 1 of the Sherman Antitrust Act (15 U.S.C. § 1) for their roles in conspiracies to fix prices, rig bids, and allocate customers for certain generic drugs (Glyburide and Doxycycline Hyclate DR). The criminal actions are styled *U.S. v. Glazer* (16cr506) and *U.S. v. Malek* (16cr508), and are pending in the United States District Court in the Eastern District of Pennsylvania.

16. Malek and Glazer have now entered plea agreements admitting that between April 2013 through December 2015, each engaged in a conspiracy to allocate customers, rig bids, and

fix and maintain prices of doxycycline hyclate, and a similar conspiracy between April 2014 and December 2015 concerning glyburide. Their plea agreements provide for cooperation in any federal investigation involving violations of criminal and antitrust law concerning “the production and sale of generic pharmaceuticals in the United States.” In exchange, the government promised immunity from criminal prosecution regarding doxycycline hyclate, glyburide, or any generic pharmaceutical product enumerated on a list filed under seal.

17. Reportedly, the DOJ is preparing additional cases involving other generic drugs.

18. On December 15, 2016, several states’ attorneys general (including the New York Attorney General), filed a civil action for violations of the Sherman Act against Heritage and other sellers of Glyburide and Doxycycline Hyclate DR, including Defendants Teva and Mylan. The action filed by the attorneys general is styled *The State of Connecticut, et al., v. Aurobindo Pharma USA, Inc., Citron Pharma, LLC, Mylan Pharmaceuticals USA, Inc. and Teva Pharmaceuticals USA, Inc., Heritage Pharmaceuticals, Inc., and Mylan Pharmaceuticals, Inc.*, and is pending in the United States District Court for the District of Connecticut (16-cv-2056) (the “State AG Action”).

19. The multistate group of plaintiff states includes New York, Connecticut, Delaware, Florida, Hawaii, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Nevada, North Dakota, Ohio, Pennsylvania, Virginia and Washington.

20. On March 1, 2017, the complaint filed in the AG Action was amended to add the following plaintiff-states: Alabama, Arizona, California, Colorado, Illinois, Indiana, Michigan, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, North Carolina, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, Utah, Vermont.

21. Connecticut Attorney General George Jepsen stated the following about the AG

Action:

My office has dedicated significant resources to this investigation for more than two years and has developed compelling evidence of collusion and anticompetitive conduct across many companies that manufacture and market generic drugs in the United States,” said Attorney General Jepsen. “While the principal architect of the conspiracies addressed in this lawsuit was Heritage Pharmaceuticals, we have evidence of widespread participation in illegal conspiracies across the generic drug industry. Ultimately, it was consumers – and, indeed, our healthcare system as a whole – who paid for these actions through artificially high prices for generic drugs. We intend to pursue this and other enforcement actions aggressively, and look forward to working with our colleagues across the country to restore competition and integrity to this important market.”²

22. New York Attorney General Eric T. Schneiderman stated the following about the

AG Action:

Lawsuit Alleges Widespread Conspiracy Among Competitors To Reduce Competition, Increase Prices For Generic Prescription Drugs . . .

The investigation, which is still ongoing as to a number of additional generic drugs, uncovered evidence of a broad, well-coordinated and long running series of conspiracies to fix prices and allocate markets for certain generic pharmaceuticals in the United States.³

23. According to the State AG Action, the information developed through its multi-year investigation (which is still ongoing) uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate customers for a number of generic pharmaceuticals in the U.S. Although the State AG Action focuses on Glyburide and Doxycycline Hyclate DR, it alleges that the Plaintiff States have uncovered a wide-ranging series of conspiracies

² <http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341> (December 15, 2016 Press Release).

³ <https://ag.ny.gov/press-release/ag-schneiderman-files-federal-antitrust-lawsuit-19-other-states-against-heritage> (December 15, 2016 press release).

implicating numerous different drugs and competitors, specifically Defendants Heritage, Mylan and Teva in the first complaint filed by the AGs.

24. Defendants operate, through their respective senior leadership and marketing and sales executives, in a manner that fosters and promotes routine and direct interaction among their companies. They exploited their interactions at various and frequent industry trade shows, customer conferences and other similar events, to develop relationships and sow the seeds for their illegal agreements. The anticompetitive agreements are further refined and coordinated at regular “industry dinners”, “girls nights out”, lunches, parties, and numerous and frequent telephone calls, emails and text messages.

25. This anticompetitive conduct – schemes to fix and maintain prices, allocate customers and otherwise thwart competition – has caused a significant, lasting and ultimately harmful rippling effect in the United States healthcare system, which is still ongoing today. Moreover, many of these schemes were conceived and directed by executives at the highest levels of the Defendant companies.

26. The State AG Action alleges that the anticompetitive schemes have been carried out in two principal ways: First, to avoid competing with one another and thus eroding the prices for certain generic drugs, the conspirators, including Heritage, Teva and Mylan communicated with each other to determine and agree on how much market share or which customers each competitor was entitled to. They then effectuated the agreement by either refusing to bid for particular customers or by providing a cover bid that they knew would not be successful. These schemes have the effect of reducing or eliminating competition for a particular drug, and have allowed the conspirators to maintain artificially supracompetitive prices in these markets throughout the United States.

27. Alternatively, or often in conjunction with those schemes, competitors in a particular market simply communicated -- typically either in person, by telephone, or by text message -- and agreed to collectively raise prices for a particular generic drug.

28. Most of the conspiratorial communications were intentionally done in person or telephonically, in an effort to avoid creating a record of their illegal conduct. Defendants had opportunities to communicate and collude at trade shows, customer events and smaller, more intimate dinners and meetings. When communications were made in writing, or by text message, some of the conspirators even took overt and calculated steps to destroy evidence of those communications.

29. Heritage, Teva and Mylan and other Defendants routinely sought out their competitors in an effort to reach agreement to allocate market share, maintain high prices and/or avoid competing on price. These agreements had the effect of artificially maintaining high prices for a large number of generic drugs and creating an appearance of competition when in fact none existed.

30. For example, in 2013 and 2014, Malek, then-President of Defendant Heritage, and Glazer, then-CEO and Chairman of Defendant Heritage, compiled a large list of generic drugs, including propranolol, and instructed employees to contact competitors to reach agreement to increase prices and allocate customers. Malek was responsible for contacting Defendants Teva and Mylan and did so with respect to a number of drugs, including propranolol. The employees also contacted competitors and reached agreements to raise prices.

31. For example, Malek at Heritage, asked an executive at Heritage to set up a call between Malek and the Vice President of Sales at Mylan, Bob Potter ("Potter"). Malek and Potter frequently attended the same industry events. For example, both attended the NACDS Store Expo

held every August throughout the Class Periods. Potter recommended that Malek contact Jan Bell (“Bell”) Director, National Accounts at Mylan.

32. Malek promptly connected with Bell through the website LinkedIn. Malek and Bell communicated by phone on multiple occasions and continued to communicate about various drugs including propranolol.

33. Similarly, Glazer at Heritage emailed an executive at Mylan. The Mylan executive responded with a phone number where he could be reached in England, and the two spoke the next day.

34. During the course of these communications, Heritage, Teva and Mylan executives agreed to raise prices, allocate market share and refrain from competing with one another for customers for various drugs, including propranolol. The objective was to avoid a price war which would reduce profitability for Defendants. Mylan agreed to “walk away” from at least one large national wholesaler and one large pharmacy chain to allow Heritage to obtain the business and increase its market share.

35. In addition to reaching agreements with competitors to allocate markets for a number of different generic drugs, including, propranolol, Heritage, Mylan, Teva and other Defendants routinely and as part of their regular course of business, sought and obtained agreements with competitors to fix and raise prices.

36. In addition to Mylan, Malek was also responsible for communicating with Defendant Teva, among others, which was a competitor on several of the drugs on the list, including propranolol. Malek had a direct relationship with a Teva executive and was able to successfully communicate with her and reach an agreement to raise prices on several drugs, including propranolol.

37. Both Malek and Glazer pushed Heritage employees to communicate with their competitors and obtain agreements to raise prices.

D. Receipt of Grand Jury Subpoenas and Other Information Requests from Government Entities.

38. Defendants Teva, Actavis, Par and Mylan have received grand jury subpoenas. Heritage is cooperating with the DOJ.

39. In December 2015, Endo International Inc., Defendant Par's parent, received Interrogatories and Subpoenas Duces Tecum from the Connecticut AG requesting information regarding pricing of certain of its generic products.

40. In June 2015, Actavis received a subpoena from the DOJ seeking documents and other information relating to the marketing and pricing of certain of its generic products and communications with competitors about such products.

41. On June 21, 2016, Teva received a subpoena from the DOJ seeking documents and other information relating to the marketing and pricing of certain of Teva's generic products and communications with competitors about such products.

42. On July 12, 2016, Teva received a subpoena from the Connecticut AG seeking documents and other information relating to potential state antitrust law violations. Defendant Actavis has also received a similar subpoena from the Connecticut AG.

43. On October 7, 2016, Mylan disclosed in a filing with the U.S. Securities and Exchange Commission ("SEC") that on September 8, 2016, the DOJ "subpoenaed a company subsidiary, a senior executive and other employees about alleged price fixing and also executed multiple search warrants related to its probe." Mylan further disclosed that the DOJ is seeking "additional information relating to the marketing, pricing and sale of" several generic drugs,

including Propranolol, cidofovir, glipizide-metformin, and verapamil “and any communications with competitors about such products.”

44. On January 24, 2017, the State of New Hampshire sent a Notice of Intent to File Civil Enforcement Action against Teva based on alleged violations of the New Hampshire Consumer Protection Act, which arise from unfair and deceptive conduct, actions and methods of competition in relation to generic drug markets.

45. On February 2, 2017, the State of South Carolina notified Teva that it is considering pursuing actions against the company under state and federal antitrust and consumer protection laws.

II. PARTIES

46. Plaintiff FWK is an Illinois limited liability company located in Glen Ellyn, Illinois. FWK is the assignee of antitrust claims possessed by Frank W. Kerr Company (“Kerr”) and brings this action as successor-in-interest to Kerr’s claims arising from its purchase of propranolol capsules directly from Defendants Actavis and Breckenridge, and propranolol tablets directly from Defendants Heritage, Teva and Mylan during the Class Periods at artificially inflated prices. As a direct and proximate result of Defendants’ collusion, manipulative conduct, and unlawful acts, FWK was injured in its business or property.

47. Plaintiff CCI is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the Class Period, CCI purchased propranolol tablets directly from Defendant Mylan at artificially inflated prices. As a direct and proximate result of Defendants’ collusion, manipulative conduct, and unlawful acts, CCI was injured in its business or property.

48. Defendant Actavis Elizabeth, LLC (“Actavis”) is a Delaware limited liability company with its principal place of business at 200 Elmora Ave., Elizabeth, NJ 07207. At the beginning of the Propranolol Capsules Class Period, Actavis was a subsidiary of Actavis, plc. In March 2015, Actavis, plc completed a merger with Allergan, plc (“Allergan”) and adopted Allergan’s name. In August 2016, Teva (defined below) purchased the Actavis Generics business, which included Defendant Actavis, from Allergan. Actavis is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., an Israeli corporation with its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel (“Teva Israel”). During the Class Periods, Actavis sold propranolol tablets and capsules in this District and throughout the United States.

49. Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, PA 19454. Teva is an indirect wholly-owned subsidiary of Teva Israel. During the Propranolol Tablets Class Period, Teva sold propranolol tablets in this District and throughout the United States. Teva divested all propranolol tablets to Global (Impax) Pharmaceuticals in August 2016.

50. Defendant Pliva, Inc. (“Pliva”) is a New Jersey corporation with its principal place of business at 72 Deforest Ave, East Hanover, NJ 07936. Pliva, Inc. is an indirect wholly-owned subsidiary of Teva Israel. During the Propranolol Tablets Class Period, Pliva sold propranolol tablets in this District and throughout the United States.

51. In this Complaint, Teva and Pliva will be referred to collectively as “Teva.” Teva maintains an office in this District at 145 West 57th Street, NY, NY 10019.

52. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. Defendant Mylan Inc. is indirectly wholly owned by Mylan N.V., a Netherlands corporation with global headquarters in Hertfordshire, U.K.,

and in Canonsburg, Pennsylvania. During the Propranolol Tablets Class Period, Mylan Inc. sold propranolol tablets in this District and throughout the United States through its subsidiaries, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc.

53. Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Defendant Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc., which is indirectly wholly owned by Mylan N.V. During the Propranolol Tablets Class Period, Mylan Pharmaceuticals Inc. sold propranolol tablets in this District and throughout the United States.

54. Defendant UDL Laboratories, Inc. (“UDL”) is an Illinois corporation with its principal place of business at 1718 Northrock Ct, Rockford, IL 61103. UDL, n/k/a Mylan Institutional Inc., is a wholly-owned subsidiary of Mylan Inc., which is indirectly wholly owned by Mylan N.V. During the Propranolol Tablets Class Period, UDL sold propranolol tablets in this District and throughout the United States.

55. In this complaint, Defendants Mylan Inc., Mylan Pharmaceuticals Inc. and UDL will be referred to collectively as “Mylan.” Mylan maintains an office in this District at 405 Lexington Avenue, NY, NY 10174.

56. Defendant Par Pharmaceutical, Inc. (“Par”), is a New York corporation with its principal place of business in Chestnut Ridge, New York. During the Propranolol Tablets Class Period, Endo International PLC’s (“Endo”) subsidiary, Qualitest Pharmaceuticals, Inc. (“Qualitest”), sold propranolol tablets in this District and throughout the United States. In September 2016, Endo completed an acquisition of Par at which time it created a combined U.S. Generics segment that included Par and Qualitest, naming the segment Par Pharmaceutical, Inc.,

an Endo International Company. Qualitest merged into Par. In this complaint, Defendant Par and Qualitest will be referred to collectively as “Par.”

57. Defendant Heritage Pharmaceuticals Inc. (“Heritage”) is a Delaware corporation with its principal place of business at 12 Christopher Way #300, Eatontown, NJ 07724. During the Propranolol Tablets Class Period, Heritage sold propranolol tablets in this District and throughout the United States. Heritage is registered to do business in New York and does business in this District. Heritage is a wholly owned subsidiary of Emcure Pharmaceuticals Ltd., an Indian corporation.

58. Heritage sold substantial amounts of propranolol in New York throughout the relevant period. Data available on the website of the Centers for Medicare & Medicaid Services reflect that New York Medicaid authorities paid over 100,000 claims for the use of propranolol manufactured by Heritage between 2010 and September of 2016, not including purchases of propranolol paid for by Medicare, private insurers or directly by consumers.

59. Defendant Breckenridge Pharmaceutical, Inc. (“Breckenridge”) is a Delaware corporation with its principal place of business at 1 Passaic Ave, Fairfield, NJ 07004. During the Propranolol Capsules Class Period, Breckenridge sold propranolol capsules in this District and throughout the United States. Breckenridge maintains an office in this District at 60 E. 42nd Street, Suite 5210, New York, NY 10165. Breckenridge is wholly owned by Pensa Pharma S.A.

60. Defendant Upsher-Smith Laboratories, Inc. (“Upsher-Smith”) is a Minnesota corporation with its principal place of business at 6701 Evenstad Drive, Maple Grove, MN 55369. During the Propranolol Capsules Class Period, Upsher-Smith sold propranolol capsules in this District and throughout the United States and has a sales person responsible for sales in New York, Amanda Strow, CNS Account Sales Manager. Upsher-Smith representatives regularly attended

trade association events in New York during the Propranolol Capsules Class Period. For example, Scott Hussey, Senior Vice President, Sales, and Jim Maahs, Vice President, Commercial Portfolio Management, attended the NACDS annual NYC Week and annual foundation dinner in New York City on December 3, 2013, 2014, 2015. Brad Leonard, Senior Director, National Accounts, attended the 2015 NACDS annual NYC Week and annual foundation dinner in New York in 2015.

61. Upsher sold substantial amounts of propranolol in New York throughout the relevant period. Data available on the website of the Centers for Medicare & Medicaid Services reflect that between 2010 and September of 2016 New York Medicaid authorities paid over 15,000 claims for the use of propranolol manufactured by Upsher, not including purchases of propranolol paid for by Medicare, private insurers or directly by consumers.

62. Whenever in this Complaint reference is made to any act, deed, or transaction of any corporation, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the management, direction, control, or transaction of the corporation's business or affairs.

A. Agents and Co-Conspirators

63. Each Defendant acted as the principal of, or agent for, all other Defendants with respect to the acts, violations, and common course of conduct described in this Complaint.

64. Various other persons, firms, companies, and corporations not named as Defendants knowingly and willingly conspired with Defendants, and performed acts and made statements in furtherance of the conspiracy and the alleged anticompetitive conduct.

65. The wrongful acts alleged to have been done by any one Defendant or co-conspirator were authorized, ordered, or done by its directors, officers, managers, agents,

employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

III. JURISDICTION AND VENUE

66. Plaintiffs bring this action to recover treble damages, attorneys' fees, litigation expenses, and court costs. Plaintiff CCI also seeks to secure injunctive relief for violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, pursuant to Sections 4 and 16 of the Clayton Act of 1914 ("Clayton Act"), 15 U.S.C. §§ 15 and 26.

67. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

68. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Periods, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affecting interstate trade and commerce, discussed below, has been carried out in this District.

69. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

70. This Court has personal jurisdiction over each Defendant, because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy throughout the United States and including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. INTERSTATE TRADE AND COMMERCE

71. Defendants are the leading manufacturers and suppliers of propranolol capsules and tablets sold in the United States.

72. Propranolol capsules and tablets are produced by or on behalf of Defendants or their affiliates in the United States and/or overseas.

73. During the Class Periods, Defendants, directly or through one or more of their affiliates, sold propranolol capsules and tablets throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

74. The activities of Defendants and their co-conspirators were within the flow of, intended to, and had a substantial effect on interstate commerce in the United States.

75. Defendants' and their co-conspirators' conduct, including the marketing and sale of propranolol capsules and tablets, took place within, and has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

76. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce in that Defendants deprived Plaintiffs of the benefits of free and open competition in the purchase of propranolol within the United States.

77. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices and allocate customers for propranolol capsules and tablets, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing propranolol prices and customer allocation, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

V. FACTUAL ALLEGATIONS

A. Overview of the Generic Drug Market

1) Generic drugs should lead to lower prices

78. Brand name drugs are typically patented and the patent owner can charge a monopoly price. After the patent expires, generic drugs enter the market. Generic drugs typically provide consumers with a lower cost alternative to brand name drugs while providing the same treatment. Specifically:

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or “therapeutic equivalence,” of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand name product.

FDA, Generic Drugs: Questions and Answers, *available at* <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>.

79. Further, “[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.” *Id.*

80. Generic versions of brand name drugs are priced significantly below the brand versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must

be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act.

81. Before the propranolol capsule and tablet conspiracies began, the FDA has recognized that “[g]eneric competition is associated with lower drug prices[.]” A Federal Trade Commission study reached the same conclusion finding that in a “mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices.” Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average 90% within a year. As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generic accelerates as more generic options are available to purchasers.

82. A mature generic market, such as the market for propranolol, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.⁴ Over time, generics' pricing nears the generic manufacturers' marginal costs.

83. Generic competition usually enables purchasers to purchase generic versions of the

⁴ See, e.g., FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at 17 (Aug. 2011) (“[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price.”); Congressional Budget Office, “How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry” (July 1998).

brand drug at a substantially lower price than the brand drug. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system \$1.68 trillion between 2005 and 2014.

2) Pricing of Generic Pharmaceuticals

84. The pricing of prescription pharmaceutical products in the U.S. is governed by institutional features typically not present in the marketplace for other consumer products.

85. Ordinarily, the price for a consumer product is set by the retailer based on the amount the typical consumer is willing to pay. Because of the unique features of the prescription drug marketplace, however, pricing of prescription drugs for most consumers is not determined between the retailer and the consumer. Rather, because most consumers' prescription drug purchases are reimbursed by public or private health plans, the pricing for prescription drugs is determined by reimbursement agreements between these prescription drug payors, *i.e.*, health plans and their prescription benefit managers, and the pharmacies that dispense drugs to the payors' insured consumers.

86. At one time, payors relied on cost-based pricing metrics to reimburse pharmacies that dispensed drugs to their insured consumers, paying the dispensing pharmacies an amount based on the manufacturer's list price for the drug, plus a small mark-up and/or dispensing fee. Over time, however, it was learned that the list price for most generic drugs published by their manufacturers was substantially higher than the actual cost incurred by pharmacies to acquire the drugs.

87. To reduce the cost of prescription drugs to the public, prescription drug payors developed Maximum Allowable Cost prices (“MACs”) to determine the amount that pharmacies would be reimbursed for dispensing generic pharmaceuticals. The MAC price refers to the maximum amount that a payor will reimburse a pharmacy for a given strength and dosage of a generic drug or brand name drug that has a generic version available. A MAC price thus represents the upper limit that a prescription drug payor will pay a pharmacy for a generic drug.

88. Payors set the MAC price of a drug based on a variety of factors, including, most significantly, the lowest acquisition cost for each generic drug paid by retail pharmacies purchasing from a wholesaler for each of a drug’s generic versions.

89. MAC pricing is designed to incentivize pharmacies to purchase the least costly version of a generic drug available in the market, without regard to the manufacturer’s list price. Because the reimbursement amount to a pharmacy is limited by the MAC price for a generic drug regardless of the pharmacy’s acquisition cost, a pharmacy’s profit will be reduced, or lost altogether, if it purchases other than the lowest cost generic product. Alternatively, if a retail pharmacy purchases the lowest priced generic version of the drug, it will maximize its profit.

90. MAC pricing also incentivizes an individual generic manufacturer to refrain from unilaterally increasing its prices. Because MAC pricing bases reimbursement on the generic drug’s lowest acquisition cost, a generic manufacturer that unilaterally increases its price for a drug will swiftly lose sales to a competing generic manufacturer whose price remains constant.

91. Consequently, in the absence of coordinated pricing activity among generic manufacturers, an individual manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales.